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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/303,518 | 04/30/1999 | VINCENZO SCARLATO | CHIR-0160 | 8470 |

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EXAMINER

ZHOU, SHUBO

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/25/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/303,518

Applicant(s)

SCARLATO ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Restriction/Election Requirement

Upon reconsideration of the previous restriction requirement mailed 5/26/2000, it is noted that several claims were not included in at least one group nor was the restriction groupings generally selected as normally selected in such sequence cases. Therefore, the restriction requirement, and previously responded to is hereby withdrawn and replaced with the restriction requirement as set forth below.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, and 4-6, drawn to proteins, classified in Class 530, subclass 300 and 350. If this group is elected, then the below sequence election requirement also is required.

II. Claims 2-3, and 8-13, drawn to polynucleotides, classified in Class 536, subclass 23.1. If this group is elected, then the below sequence election requirement also is required.

III. Claim 7, drawn to antibody, classified in Class 530, subclass 387.1. If this group is elected, then the below sequence election requirement also is required.

IV. Claims 14-16, drawn to compositions, vaccine compositions and pharmaceutical compositions, classified in Class 424, subclasses 184.1 or 130.1. If this group is elected, then the below sequence election requirement also is required. Further, if this group is elected, the below species election requirement is also applied.

V. Claim 17, drawn to use of a composition comprising a protein, a nucleic acid molecule, or an antibody in the manufacture of a medicament for the treatment and prevention of bacterial infection, classified in Class 514, subclasses 2, 44 or 130.1. If this group is elected, then the below sequence election requirement also is required. Further, if this group is elected, the below species election requirement is also applied.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, III and (IV and V) are independent/distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is polypeptides; for Group II, the critical feature is nucleic acids; for Group III, the critical feature is antibody; and for Groups (IV and V), the critical feature can be polypeptide, nucleic acid, or antibody. It is acknowledged that various processing steps may cause a polypeptide of Group I to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of the nucleic acid and polypeptide Groups support the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides and antibody have been most commonly, albeit not always, separately characterized and published in the biochemical and biomedical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the Groupings of I, II, III and (IV and V) are independent and/or distinct invention types for restriction purposes.

The inventions of Groups IV and V are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant

case, the composition of Group IV can be used in the processes of the inventions of Group V, i.e. used in the manufacture of a medicament for the treatment or prevention of infection of bacteria. Alternatively, if the species of nucleic acid is elected as responding to the below summarized species election requirement, the inventions of Group IV can be used in hybridization to isolate new genes, etc., which is clearly a distinct usage of such nucleic acids.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleic acid sequences, the Applicant(s) may elect 10(TEN) nucleic acid sequences (See MPEP 803.04).

Examination will be restricted to only the elected sequences.

Additional Specie Election only regarding an election of Group IV or V above

It is noted that the claims of Group IV and V contain multiple species of inventions which require restriction/election. Claims 14-17 are directed to compositions comprising proteins, nucleic acids or antibody and the methods of using the same. This list of components are considered as species subject matter because they are distinct chemical types as set forth above. Further, these components are usually published separately and require different searches, which would impose an undue search burden to the Office. Applicant is required to elect only one species for the

claimed inventions of Claims 14-16 is Group IV is elected, or claim 17 if Group V is elected. The species are (1) protein, (2) nucleic acids, and (3) antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Doreen Truhillo on February 8, 2002, applicants did not make an election but rather preferred receiving a restriction requirement in writing prior to election.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER

S. "Joe" Zhou, Ph.D.
Patent Examiner

